

REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1-27 were in this application, claims 14-27 were withdrawn in response to a restriction requirement, claim 1 has been amended and claims 2, 5, 8 and 9 have been cancelled.

The Examiners comment concerning trademark usage is acknowledged and appropriate corrections to the specification have been made.

Claims 1-13 were rejected as being indefinite as claim 1 was not clear that the L-glutamine and L-glycine were added to the aloe extract which includes acemannan. Claim 1 has been amended to clarify the relationship between the ingredients, and this rejection is rendered moot.

The anticipation rejections of claims 1, 8, 12 and 13, (paragraphs 6, 7 and 8), and claims 1, 4, 8, 9, 12 and 13 (paragraph 9) are rendered moot by the amendment of claim 1 which incorporates the limitations of claims 2, 5, 8 and 9 therein.

Claims 1-7 and 9-12 were rejected as being obvious over the Herbal Fields web site, describing Aloe vera.

The applicants' invention is an oral composition formulated for oral administration, and containing specific ingredients, not Aloe extract alone. There is no teaching or suggestion for preparing such a mixed composition on the Herbal Fields website, and absent a teaching or suggestion for doing as the applicants have done, claim 1 and the claims dependant therefrom are not rendered obvious. In particular, varying the amount of aloe vera alone cannot produce the applicants claimed composition, and this rejection should be withdrawn.

Claims 1-7 and 9-12 were rejected as being obvious over the CSL web site, describing Aloe vera.

The examiner admits the CSL web site does not teach the ingredients in the amounts claimed by the applicant, but alleges that this is just "optimizing" to achieve the pharmaceutical effects taught by the reference. However, the reference offers no such teaching for including specific amounts of L-glutamine and L-glycine with an aloe vera extract, nor does it teach the treatment of the symptoms of upper intestinal pain and cramping. There is nothing to lead one to

optimize the amounts of these particular ingredients, to the exclusion of others. Aloe vera, as the examiner found, contains many ingredients, and there is nothing to teach or suggest which of these might be supplemented to create a composition that effectively treats upper intestinal pain and discomfort as discovered by the applicants. Neither the suggestion nor the expectation of success are found in the reference, rather it is only found in the applicants disclosure, and claims 1-7 and 9-12 are not obvious over the CSL website.

Claims 1-7 and 9-12 were rejected as being obvious over WO 00/00186.

WO 00/0186 describes topical formulation for promoting wound healing, and presents no discussion concerning orally administered compositions, and certainly does not teach or suggest to one skilled in the art such a composition as presented in applicants' claim 1. Consequently, claim 1 and the claims dependant therefrom are not rendered obvious over WO 00/00186.

Claims 1-7 and 9-12 were rejected as being obvious over US Pat. Publication 2003/0084912.

In order to uphold a finding of obviousness, there must be some teaching, suggestion or incentive for doing what the applicants have done. A.C.S. Hospital Sysys. Inc. V. Montefior Hospital, 723 F.2d 1572 (Fed. Cir. 1984). It is not within the framework of 35 U.S.C. §103 to pick and choose from the prior art only so much as will support a holding of obviousness to the exclusion of other parts necessary for full appreciation of what the prior art teaches or suggests, as hindsight is not the test. In re Wesslau, 353 F.2d 238 (CCPA 1965). Also, "both the suggestion and the expectation of success must be found in the prior art, not in the applicants' disclosure". In re Dow Chemical Co., 837 F.2d 469 (Fed. Cir. 1988).

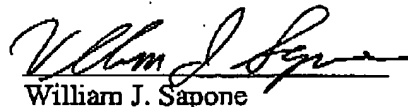
"[C]iting references which merely indicate that isolated elements and/or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. That is to say, there should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention." Ex parte Hiyamizu, 10 U.S.P.Q. 2d 1393 (POBA 1988).

The U.S. Publication is directed to a product for reducing tobacco smoking that utilizes an antioxidant which can be selected from a long list of materials. It is difficult to perceive how

one skilled in the art would pick and choose among the numerous antioxidant ingredients to arrive at the applicants' invention. There is no teaching or suggestion for producing the applicants' claimed composition, nor any discussion of the compositions' beneficial effects. This is clearly a hindsight reconstruction of the applicants' invention which is an improper basis for rejecting the claims, and claims 1-7 and 9-12 are patentable over this citation.

Based on the above remarks, favorable consideration and allowance of the application is respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



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**MARKED UP SPECIFICATION PARAGRAPHS**

Page 3, third full paragraph:

One aloe extract that is useful in the present invention is Manapol<sup>TM</sup> ® aloe vera extract available from Carrington Laboratories, Inc. that contains roughly 25% acemannan, 25% pectin, 25% methyl cellulose and 25% calcium malate. Of course other aloe extracts that have therapeutically effective quantities of acemannan may also be used.

Page 4, second full paragraph:

A combination of glutamine and aloe vera extract was given to an individual who had upper intestinal tract discomfort. The individual was given 80 mg. of Manapol<sup>®</sup> aloe vera extract and 1 gram of L-glutamine. While the upper abdominal pain resolved completely within 15 minutes, the relief was of limited duration and the discomfort returned in full force within a few hours.

Paragraph Bridging pages 4 and 5:

A person suffering from upper intestinal tract discomfort was given eight ounces of the inventive formulation comprising aloe vera extract containing 320 mg Manapol<sup>®</sup> aloe vera extract, 250 mg. of L-glycine and 1 gram of glutamine. The person reported complete relief for an entire day. The next day only the aloe extract and L-glutamine were administered, and again the relief was of short term duration. Return to the three component mixture brought repeated complete daily relief. Only with the combination of all three ingredients was complete all day duration relief achieved.

Page 5, second full paragraph:

The aloe vera extract preferably contains accmannan and is given at from about 30-300 mg., more preferably about 50-150 mg. and most preferably 60 mg. per day. This may be adjusted to account for the proportion of acemannan in the extract. For example, as Manapol aloe vera extract contains about 25 % wt. acemannan, then 40 mg. of aloe vera extract would contain 10 mg. acemannan, and the ranges described above may be adjusted to allow use of other aloe vera extracts while still providing comparable quantities of acemannan in the inventive formulation. In a preferred embodiment, the composition is administered in a tableted formulation containing 30 mg aloe vera extract, such as Manapol aloe vera extract (approx. 7.5 mg acemannan), 250 mg L-glycine, and 300 mg L-glutamine. Administration can be of two tablets together, though use of one tablet twice daily is preferred.

Page 7, first full paragraph:

In a preferred embodiment of the present invention, a 580 mg tablet, containing 30 mg of an aloe vera extract such as Manapol aloe vera extract, 300 mg glutamine, and 250 mg glycine, as well as microcrystalline cellulose, silica and magnesium stearate, is given on a twice daily.